

**REMARKS**

Appreciation is expressed to Examiner Prema Mertz for the courteous interview of earlier this morning. The following summarizes that discussion.

It seems that the rationale underpinning the examiner's obviousness rejection is that: the prior art teaching that detection of elevated ANF levels is correlated with the existence of sepsis would make it obvious that one of ordinary skill in the art could measure increased levels of pro-ANF, and such elevated levels of such pro-hormone would also be correlated with the existence of sepsis. The examiner cites U.S. '617 to support this proposition, noting that the latter patent teaches that a different pro-hormone, procalcitonin, is also correlated with the existence of sepsis when detected at increased levels. However, in actuality, U.S. '617 is inconsistent with this rationale.

During the interview, the passage at column 2, lines 21-26 was discussed. For convenience, this is repeated below:

At the same time in the case of a sepsis no increased calcitonin concentrations are observed according to the invention, which is remarkable for the reason that up to the present, as a rule, procalcitonin was regarded as calcitonin precursor, the appearance of which also leads to a calcitonin formation.

If procalcitonin is correlated with sepsis but the corresponding hormone itself, calcitonin, is not correlated with sepsis, then a skilled worker cannot reasonably conclude from the taught correlation of ANF with sepsis that its pro-hormone would somehow also be correlated with sepsis. U.S. '617 shows that the pro-hormone and the underlying hormone in the case of calcitonin have different relationships to the

existence of sepsis. Thus, the examiner's rationale is not supported by the references. Since there is no other basis for the examiner's contention, it can be seen that the rejection must be withdrawn.

Moreover, as previously discussed, just because a given pro-hormone is shown to be correlated with sepsis, this does not mean that all pro-hormones or any particular other pro-hormone is also correlated with sepsis, irrespective of whether the corresponding hormone is or is not so correlated.

**Request for withdrawal of finality of the Office Action**

It is believed that the foregoing arguments establish the patentability of the current claims over the references and the examiner's rationale. However, if the examiner is to maintain the rejection, it is respectfully submitted that a new Office Action be submitted and not an Advisory Action. This is because the finality of the outstanding Office Action is premature.

In the Advisory Action of May 1, 2008, the examiner checked box number 7 indicating that the proposed prior amendments would not be entered and that all claims remained rejected. Subsequently, applicant's prior representative filed an RCE on May 21, 2008 using the prior response under 37 C.F.R. § 1.116 on April 21, 2008 as the requisite submission, apparently based on the examiner's checking of box number 7. Further, apparently, the PTO also treated the mentioned prior response as the requisite submission since the RCE was accepted by the PTO.

However, it has now been noted that since no amendments were made in the mentioned prior response under 37 C.F.R. § 1.116, that perhaps an error was involved

on the part of the prior representative and the PTO. In other words, a different submission perhaps should have been filed with the RCE. In either event, the outstanding Office Action should not have been final.

To the extent such action will expedite the examiner's handling of prosecution, applicants hereby authorize the entrance in an Examiner's Amendment of the following new claim 11 which is based on original claim 5.

11. The method of claim 8 wherein said determination of the level of pro-ANF is carried out as an immunoassay or a precipitation assay.

If any other action is deemed necessary by the PTO in order to ensure a proper consideration of this response, the examiner is courteously requested to telephone the undersigned.

Respectfully submitted,

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